**UNITED STATES DISTRICT COURT**
**DISTRICT OF MASSACHUSETTS**

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| IN RE OCULAR THERAPEUTIX, INC. SECURITIES LITIGATION<br><br>This Document Relates To: All Actions | Case No. 1:17-cv-12288-GAO<br><br>**ORAL ARGUMENT REQUESTED**<br><br>Leave to File Excess Pages Granted on July 2, 2018 |

**MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS THE CONSOLIDATED AMENDED CLASS ACTION COMPLAINT**

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Defendants Ocular Therapeutix, Inc. ("Ocular" or the "Company"), Amarpreet Sawhney, George Migausky, Andrew Hurley and Eric Ankerud (the "Individual Defendants") (collectively, the "Defendants") respectfully submit this memorandum in support of their motion to dismiss the Consolidated Amended Class Action Complaint (the "Complaint" or "Compl.").

## I. INTRODUCTION

Ocular is a Massachusetts-based biopharmaceutical company that is seeking U.S. Food and Drug Administration ("FDA") approval to market its drug candidate DEXTENZA for the treatment of post-surgical ocular pain and inflammation. In July 2017, two investor websites published articles regarding manufacturing issues that the FDA allegedly observed during an inspection of Ocular's facilities. Shortly thereafter, Ocular announced the disappointing news that the FDA had determined that it could not approve Ocular's marketing application for DEXTENZA in its present form. In its announcement, Ocular noted that the FDA did not identify any efficacy or safety concerns with DEXTENZA, but had reached its decision in light of issues identified during a May 2017 inspection that remained outstanding.

From this, Plaintiffs seek to concoct a claim of securities fraud. They allege that Defendants knew as early as March 2016, but never disclosed, that the Company's manufacturing practices were inadequate and that resolving the issues that the FDA had raised would delay FDA approval. Plaintiffs claim that, despite this alleged knowledge, Defendants defrauded investors by concealing this information, "downplaying" the purported significance of the FDA inspectional observations, and expressing optimism about DEXTENZA's prospects.

As set forth below, the Complaint fails to allege fraud. To begin with, the Complaint is devoid of the required well-pleaded, contemporaneous facts establishing that, at the time of the challenged statements, Ocular was unable to address the FDA's inspectional observations or that its efforts to obtain FDA approval were doomed to fail. Plaintiffs' allegations do not even

purport to rely on internal documents, but instead proceed purely from hindsight, fundamentally flawed inferences, and a purported confidential witness who does not have first-hand knowledge of any relevant fact. Plaintiffs also impermissibly seek to hold two Individual Defendants (Messrs. Migausky and Hurley) liable solely based on statements made by others, without offering any well-pleaded allegations that either controlled the content of any challenged statement, and even though Mr. Migausky did not join Ocular until more than a year into the class period.

Equally fatal to the Complaint, Plaintiffs offer nothing to support the required cogent and compelling inference of scienter. Plaintiffs' claim that Defendants were consciously lying or reckless as to the truth of the challenged statements largely rests on the same hindsight allegations that do not even show a false or misleading statement in the first place. Aside from this, Plaintiffs offer only routinely rejected "must have known" status allegations. For these and the other reasons set forth below, the Court should dismiss the Complaint with prejudice.

## II. BACKGROUND FACTS[1]

### A. Ocular's Business And Efforts To Obtain FDA Approval

Ocular is a Massachusetts-based biopharmaceutical company that focuses on the development and commercialization of therapies for diseases and conditions of the eye. Compl. ¶¶ 2, 23. In September 2015, Ocular submitted a New Drug Application ("NDA") to the FDA seeking approval to market DEXTENZA for the treatment of post-surgical ocular pain.[2] *Id.* ¶¶ 3, 30. In February 2016, per usual procedure, the FDA conducted an inspection of Ocular's

[1] Defendants accept the factual allegations of the Complaint solely for purposes of this motion. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

[2] An NDA is application through which a drug sponsor formally proposes that the FDA approve a new drug for sale and marketing in the United States. *See* FDA, "New Drug Application (NDA)," https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/NewDrugApplicationNDA/default.htm (last accessed July 4, 2018).

facilities and subsequently issued inspectional observations to Ocular on FDA Form 483 (the "February 2016 Form 483").[3] Compl. ¶¶ 5, 31. In March 2016, Ocular disclosed that it had received this Form 483 "focused on process controls, analytical testing and physical security procedures related to manufacture of our drug product." Ex. A at 85; *see* Compl. ¶¶ 42-43.[4] The Company reported that it had "addressed some observations before the inspection was closed and [had] responded to the FDA with a corrective action plan." Ex. A at 85. But it also warned that "[t]he failure to resolve the Form 483 inspectional observations from the February 2016 inspection could result in a delay in the . . . potential approval for the [DEXTENZA] NDA." *Id.*

In July 2016, Ocular received a Complete Response Letter (the "2016 Complete Response Letter") from the FDA declining to approve Ocular's NDA in its present form. Compl. ¶ 45.[5] At that time, Ocular disclosed that it "previously responded to all requests in an effort to address the manufacturing items raised by the FDA" and "will continue to work collaboratively with the FDA" (Ex. B at 1), but that approval of the DEXTENZA NDA could nonetheless be affected by "deficiencies in manufacturing process and controls identified during" the FDA's inspection. *Id.* s*ee* Compl. ¶ 45. Approximately one month later, on August 9, 2016, Ocular issued a press release and Form 8-K describing a further FDA letter about Ocular's

[3] The FDA issues a Form 483 at the conclusion of an inspection when its investigators have observed conditions that may, in their judgment, constitute violations of the Food Drug and Cosmetic Act and related Acts. The FDA Form 483 is presented and discussed with the company's senior management, and companies are encouraged to respond to the FDA Form 483 in writing with their corrective action plan and then implement that corrective action plan. *See* FDA, "FDA Form 483 Frequently Asked Questions," https://www.fda.gov/ICECI/Inspections/ucm256377.htm (last accessed July 4, 2018); *see also* Compl. ¶ 29.

[4] All exhibits referenced herein ("Ex.") are attached to the Declaration of Peter J. Kolovos, filed herewith. These exhibits are all either documents cited or referenced in the Complaint or other SEC filings by Ocular. On a motion to dismiss, "courts must consider . . . documents incorporated into the complaint by reference, and matters of which the court may take judicial notice." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007). Courts routinely take judicial notice of statements contained in a defendant's regulatory filings on a motion to dismiss. *See, e.g., In re Stone & Webster, Inc. Sec. Litig.*, 253 F. Supp. 2d 102, 128 n.11 (D. Mass. 2003) (taking judicial notice of SEC filings in deciding motion to dismiss).

[5] The FDA sends a Complete Response Letter to a drug applicant "if the agency determines that [it] will not approve the application or abbreviated application in its present form for one or more of the reasons given in" the relevant provisions of the Code of Federal Regulations. 21 C.F.R. § 314.110(a).

responses to the Form 483 observations. Ex. C at 1. Ocular indicated that, according to the FDA letter, the Company's corrective actions to date "appear to address" the FDA's inspectional observations, with one exception "relat[ing] to the proposed process for identity testing of an incoming inert gas component used in the DEXTENZA manufacturing process." *Id.*; *see also* Compl. ¶ 69.

Ocular resubmitted its DEXTENZA NDA to the FDA on January 23, 2017. Compl. ¶ 46. The FDA conducted another inspection of Ocular's facilities between April 24 and May 4, 2017 (Compl. ¶ 48) and on May 4, 2017, the FDA issued a second FDA Form 483 to Ocular (the "May 2017 Form 483"). *Id.* During an earnings call the very next day, the Company reported that it had received this second Form 483, noted that it planned to respond to the FDA with corrective action plans, but again cautioned that "timely resolution of the 483 observations is a prerequisite" to FDA approval. Ex. D at 2.

On July 6, 2017, the investor website *Seeking Alpha* published an article regarding Ocular and the May 2017 Form 483. Compl. ¶¶ 60-62. The article expressed concern about the manufacturing issues described in the May 2017 Form 483 and questioned Ocular's approach to manufacturing. On the same day, the website *STAT* published an article regarding the possibility that the FDA could reject the DEXTENZA NDA. *Id.* ¶ 9. On July 12, 2017, the FDA issued a Complete Response Letter (the "2017 Complete Response Letter") to Ocular, which set forth the FDA's determination that it could not approve Ocular's NDA for DEXTENZA in its present form. Compl. ¶ 64. The FDA did not identify any safety or efficacy concerns for the drug, but nonetheless declined to approve the NDA because certain manufacturing issues that the FDA had identified during its most recent inspection remained outstanding. *Id.* ¶ 90.

**B. The Challenged Statements**

In an attempt to concoct a securities fraud claim in the aftermath of the 2017 Complete

Response Letter, Plaintiffs have challenged various prior Company statements, stretching back as far as March 2016, as false and misleading. Compl. ¶¶ 67-80.

*First*, Plaintiffs challenge Ocular's statement (which appears in the Form 10-Ks that the Company filed with the SEC in March 2016 and March 2017) that it manufactures its drug products using "current good manufacturing practices, or cGMP" (the "cGMP statements"). Compl. ¶¶ 67-68, 73-74.[6] Plaintiffs assert that, in light of the FDA's issuance of the two Form 483s (which Ocular also disclosed in its SEC filings), Ocular's manufacturing practices were not in compliance with cGMP. *Id.* ¶¶ 68, 74.

*Second*, Plaintiffs challenge various statements that Dr. Sawhney (Ocular's then-current Chief Executive Officer) made during the Company's November 9, 2016 earnings conference call regarding the progress that Ocular had made towards addressing the manufacturing issues the FDA identified in the February 2016 Form 483. Compl. ¶¶ 69-72. According to Plaintiffs, these statements misrepresented Ocular's actual progress and downplayed the risk that Ocular might not be able to obtain FDA approval. *Id.* ¶¶ 70, 72.

*Third*, Plaintiffs challenge various statements that Dr. Sawhney and Mr. Ankerud (Ocular's then-current Executive Vice President of Regulatory, Quality and Compliance) made during the Company's May 5, 2017 earnings conference call, during which the Company disclosed that the FDA had issued the May 2017 Form 483 and discussed the Company's plans for addressing the FDA's observations. Compl. ¶¶ 75-80. Here again, Plaintiffs assert that Defendants purportedly misrepresented Ocular's progress in addressing the FDA's observations

[6] The term cGMP "refers to the Current Good Manufacturing Practice regulations enforced by the" US Food and Drug Administration (FDA). These regulations "provide for systems that assure proper design, monitoring, and control of manufacturing processes and facilities" and following these regulations "assures the identity, strength, quality, and purity of drug products by requiring that manufacturers of medications adequately control manufacturing operations." FDA, "Facts About the Current Good Manufacturing Practices (CGMPs)," https://www.fda.gov/drugs/developmentapprovalprocess/manufacturing/ucm169105.htm (last accessed July 4, 2018).

and the prospects for obtaining FDA approval. *Id.*

## III. ARGUMENT

To state a claim under Section 10(b) and Rule 10b-5, a plaintiff must adequately plead: (1) a material misrepresentation or omission of fact, (2) made with scienter, (3) in connection with the purchase or sale of a security, (4) reliance, (5) economic loss, and (6) loss causation. *See ACA Fin. Guar. Corp. v. Advest, Inc.*, 512 F.3d 46, 58 (1st Cir. 2008) (citing *Dura Pharm., Inc. v. Broudo*, 544 U.S. 336, 341-42 (2005)); *Miss. Pub. Emps.' Ret. Sys. v. Bos. Sci. Corp.*, 523 F.3d 75, 85 (1st Cir. 2008). A complaint asserting securities fraud must comply with both the heightened pleading standards of Fed. R. Civ. P. 9(b) and the stringent procedural requirements of the Private Securities Litigation Reform Act of 1995 ("PSLRA"). *See In re Bos. Sci. Corp. Sec. Litig.*, 686 F.3d 21, 27, 30 (1st Cir. 2012); *Greebel v. FTP Software, Inc.*, 194 F.3d 185, 193-94 (1st Cir. 1999) (the First Circuit "has been notably strict and rigorous in applying the Rule 9(b) standard in securities fraud actions"). The PSLRA requires that a complaint "specify each statement alleged to have been misleading [and] the reason or reasons why the statement is misleading." *Miss. Pub. Emps.' Ret. Sys.*, 523 F.3d at 85 (quoting 15 U.S.C. § 78u-4(b)(1)); *see Greebel*, 194 F.3d at 193-94 (plaintiff must state "time, place, and content of alleged misrepresentations with specificity" and also "explain why the challenged statement or omission is misleading"); *Chalverus v. Pegasystems, Inc.*, 59 F. Supp. 2d 226, 232 (D. Mass. 1999) ("[A] securities fraud plaintiff must allege with particularity the who, what, when, where, and why of each materially false or misleading misrepresentation or omission.").

The PSLRA also requires that the complaint state with particularity facts giving rise to a "strong inference" that the defendant acted with scienter, which embraces an "intent" to defraud or "extreme recklessness" in making any material misrepresentation or omission. *City of Dearborn Heights Act 345 Police & Fire Ret. Sys. v. Waters Corp.*, 632 F.3d 751, 757 (1st Cir.

2011). A plaintiff must allege facts that make an inference of scienter "'more than merely plausible or reasonable—it must be cogent and at least as compelling as any opposing inference of nonfraudulent intent.'" *Id.* (quoting *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 314 (2007)). The court must weigh competing inferences in assessing whether a "strong inference" of scienter is raised. *Tellabs*, 551 U.S. at 314.

**A. The Complaint Fails To Allege An Actionable Misstatement Or Omission**

Plaintiffs' claim of fraud rests on the alleged existence of contemporaneous facts showing that Ocular would not be able to overcome the inspectional observations that the FDA issued to Ocular in February 2016 and May 2017 in a timely manner.[7] Thus, Plaintiffs allege that the Company's statements about its efforts to address the FDA's observations were misleading absent a disclosure that it was "highly unlikely" that the company would obtain FDA approval of DEXTENZA. Compl. ¶¶ 72, 76, 80, 103. Plaintiffs also point to the two Form 483s, and Ocular's purported inability to overcome them, as a basis for their claims about the challenged cGMP statements. But all of these claims ignore Ocular's actual disclosures and, in any event, lack any contemporaneous factual support. The claims are nothing more than impermissible fraud by hindsight based on subsequent events and FDA actions.

**1. The Challenged cGMP Statements Are Not Actionable**

Plaintiffs fail to allege adequately the factual predicate for their assertion that the challenged cGMP statements were false and misleading.[8] Plaintiffs provide no contemporaneous facts (let alone any pleaded with particularity) demonstrating that Ocular's drug manufacturing

[7] Plaintiffs also cite in passing to inspectional observations that the FDA issued to Ocular in March 2015, a year before the start of the purported class period (Compl. at 7 n.1), but do not contend that Ocular made any false statement about this earlier Form 483 or that it rendered false any challenged class period statement.

[8] In its March 2016 and March 2017 Form 10-Ks, Ocular stated, "We fabricate devices and drug depot products for use in our clinical trials, research and development and commercial efforts for all of our therapeutic product candidates using current good manufacturing practices, or cGMP, at our multi-product facility located in Bedford, Massachusetts." Compl. ¶¶ 67, 73.

practices were not compliant with cGMP when Ocular made these statements in its March 2016 and March 2017 Form 10-Ks. Plaintiffs offer no allegations from confidential witnesses or contemporaneous internal documents that might cast doubt on the truth of these statements.

Instead, Plaintiffs seek to establish falsity based on the FDA Form 483s.[9] As an initial matter, given that Ocular disclosed its receipt of the Form 483s—and actually disclosed and described the February 2016 Form 483 *in the very same March 2016 SEC filing* that includes the challenged 2016 cGMP statement—it strains logic to suggest that the cGMP statements are somehow misleading in light of the Form 483s. In any event, this argument rests on a flawed premise—the FDA's issuance of inspectional observations on Form 483s does not render the challenged cGMP statements false. Rather, courts have recognized that Form 483s are "inspectional observations, and do not represent a final Agency determination regarding [the Company's] compliance." Ex. E at 1; *see also City of Pontiac Gen. Emps.' Ret. Sys. v. Stryker Corp.*, 865 F. Supp. 2d 811, 825 (W.D. Mich. 2012) (Form 483 could not render statement regarding compliance with FDA regulations false because "the FDA does not consider observations contained in a Form 483 as a final agency determination of noncompliance. The Form 483 thus [is] not the final word on whether the . . . facility was in compliance with FDA regulations."); *McGuire v. Dendreon Corp.*, No. C07-800MJP, 2008 WL 1791381 at *7 (W.D. Wash. Apr. 18, 2008) ("Plaintiffs inappropriately conflate the . . . issuance of a Form 483 with a finding of non-compliance . . . because the Form 483 is not a final agency determination of non-compliance").

Plaintiffs' reliance on the subsequent FDA actions fares no better. Plaintiffs suggest that

[9] To the extent Plaintiffs seek to establish the falsity of the March 2017 cGMP statement based on the Form 483 that the FDA issued two months later (in May 2017), the hindsight nature of this claim (as explained below) provides an independent reason for the Court to reject it.

the FDA's July 2016 Complete Response Letter purportedly renders the March 2016 cGMP statement false and misleading, while the FDA's July 2017 Complete Response Letter similarly renders misleading the March 2017 cGMP statement. Compl. ¶¶ 45, 48, 64. According to Plaintiffs, because these FDA actions rested, at least in part, on FDA observations regarding Ocular's manufacturing process, the Company's prior statements about cGMP compliance must have been false when Ocular made them. But this is classic, and impermissible, fraud by hindsight. *See Ezra Charitable Tr. v. Tyco Int'l, Ltd.*, 466 F.3d 1, 6 (1st Cir. 2006) ("Pleading 'fraud by hindsight,' essentially making general allegations 'that defendants knew earlier what later turned out badly,' is not sufficient." (citation omitted)); *In re Sonus Networks, Inc. Sec. Litig.*, No. 04-10294-DPW, 2006 WL 1308165, at *17 (D. Mass. May 10, 2006) (declining to draw an "impermissible fraud-by-hindsight inference").

Unable to offer contemporaneous factual support to establish that Ocular's drug manufacturing practices were not cGMP-compliant, Plaintiffs resort to arguing that the challenged cGMP statements were misleading by omission. Thus, Plaintiffs contend that it was misleading for Ocular to state that it manufactured its drug products in compliance with cGMP without disclosing additional information about the observations that the FDA issued to Ocular in the February 2016 and May 2017 Form 483s. But Plaintiffs can only press their omission claims by ignoring the fulsome disclosures that Ocular ***did*** make about the FDA's observations.

Plaintiffs do not dispute that Ocular disclosed that it had received the two Form 483s, and that they both included observations related to drug manufacturing issues. Compl. ¶¶ 43, 58, 69, 75, 77. Nor can there be any real dispute that Ocular disclosed the two Form 483s in a timely manner. Ocular disclosed the February 2016 Form 483 within a month, in its next SEC filing (the March 2016 10-K), and disclosed the May 2017 Form 483 one day after the FDA issued it.

*See* Exs. A at 85, D at 2, and F at 30. *See City of Bristol Pension Fund v. Vertex Pharm. Inc.*, 12 F. Supp. 3d 225, 237 (D. Mass. 2014) (where defendants disclosed allegedly omitted facts prior to and contemporaneously with alleged omissions and misleading statements, the company had made that fact available to the market).

Further, Plaintiffs' omission argument ignores the details that Ocular actually disclosed about the subject matter of the FDA's observations. For example, in its March 2016 Form 10-K—the SEC filing which marks the start of the class period and includes the first of the challenged cGMP statements—Ocular noted that the February 2016 Form 483 contained "inspectional observations focused on process controls, analytical testing and physical security procedures related to manufacture of our drug product for stability and commercial production purposes." Ex. A at 85. Similarly, in its May 5, 2017 disclosure regarding the May 2017 Form 483, Ocular stated that it contained "inspectional observations focused on procedures for manufacturing processes and analytical testing related to manufacture of drug product for commercial production." Ex. F at 17. Then, during Ocular's earnings call that same day, Mr. Ankerud explained that the "primary focus" of the May 2017 Form 483 "relates to a particula[te] matter issue as part of our manufacturing process." Ex D. at 7. Thus, Ocular disclosed what Plaintiffs refer to the "bombshell finding" in the May 2017 Form 483—the FDA's observation about particulate matter in drug batches—the day after the FDA issued this observation.[10]

In sum, Ocular timely disclosed its receipt of the February 2016 and May 2017 Form 483s along with specific details about the FDA's observations (including their primary subject matters and purported "bombshell" findings). These disclosures belie any claim that the cGMP

[10] Ocular had no duty to belittle itself or characterize the FDA's observations in any particular way. *See Coyne v. Metabolix, Inc.*, 943 F. Supp. 2d 259, 269 (D. Mass. 2013) ("A defendant does not have a duty to cast the descriptions of its business in the most negative light.").

statements were misleading by omission, and the securities law do not require further disclosures regarding the contents of the Form 483s. *See In re First Marblehead Corp. Sec. Litig.*, 639 F. Supp. 2d 145, 155 n.73 (D. Mass. 2009) (court "must dismiss a complaint founded on allegations of securities fraud if the allegedly . . . misrepresented information was in fact appropriately disclosed" (citation omitted)); *see also Fire & Police Pension Ass'n of Colo. v. Abiomed Inc.*, 778 F.3d 228, 243-44 & n.9 (1st Cir. 2015) ("there is no per se rule that a company immediately disclose receipt of any correspondence with the FDA" and "[t]here must be some room for give and take between a regulated entity and its regulator."); *In re Sanofi Sec. Litig.*, 87 F. Supp. 3d 510, 542 (S.D.N.Y. 2015) ("interim FDA feedback is not material because it does not express a binding agency decision and is subject to change as the FDA and pharmaceutical companies work together to develop viable clinical trials and approvable licensing applications"), *aff'd sub nom. Tongue v. Sanofi*, 816 F.3d 199 (2d Cir. 2016); *In re Genzyme Corp.*, Nos. 09-cv-11299, 09-cv-11267, 2012 WL 1076124, at *10 (D. Mass. Mar. 30, 2012) ("It simply cannot be that every critical comment by a regulatory agency . . . has to be seen as material for securities law reporting purposes, especially in an industry like [defendant]'s, where there is constant and close supervision by the FDA.").[11]

**2. The Challenged Statements From The November 9, 2016 Earnings Conference Call Are Not Actionable**

Plaintiffs challenge two statements Dr. Sawhney made during the Company's November 9, 2016 earnings call concerning the progress Ocular had made in addressing the FDA's observations. Compl ¶ 69 ("We believe we have taken the appropriate steps to address the

[11] *See also In re MELA Scis., Inc. Sec. Litig.*, No. 10 CV 8774 VB, 2012 WL 4466604, at *13-14 (S.D.N.Y. Sept. 19, 2012) (no duty to disclose FDA concerns about ongoing clinical trials); *Noble Asset Mgmt. v. Allos Therapeutics, Inc.*, No. 04-cv-1030, 2005 WL 4161977, at *7 (D. Colo. Oct. 20, 2005) ("The fact that the FDA staff members raised questions did not impose a duty upon the defendants to revise their opinions about the drug's efficacy or to report to the public the substance of their conversations with the FDA."); *In re Medimmune, Inc. Sec. Litig.*, 873 F. Supp. 953, 966 (D. Md. 1995) (analyzing dialogue between FDA and drug company and concluding, "Defendants . . . had no duty to report . . . ongoing discussions with FDA during the review process").

manufacturing related items raised by the FDA . . . ."); *id.* ¶ 71 ("I think it's important to realize that this is a matter of when not if type of a thing, we've adequately we think addressed the issues that they've raised. And communicated our plans to them and they seem in broad agreement with the plans that we have communicated."). Courts have consistently deemed these sorts of loosely optimistic statements and opinion statements inactionable.[12]

**a) Puffery And Broad Statements Of Corporate Optimism Are Not Actionable**

The challenged expressions of optimism regarding Ocular's prospects for resolving the FDA's inspectional observations, which Dr. Sawhney stated in terms that are "generally optimistic but lacking in certainty or specifics," are inactionable as a matter of law. *In re Praecis Pharm., Inc., Sec. Litig.*, No. 04-12581-GAO, 2007 WL 951695, at *8 (D. Mass. Mar. 28, 2007); *compare* Compl. ¶ 69 ("We believe we have taken the appropriate steps to address the manufacturing related items raised by the FDA . . . .") and *id.* ¶ 71 ("I think it's important to realize that this is a matter of when not if type of a thing, we've adequately we think addressed the issues that they've raised."), *with Corban v. Sarepta Therapeutics, Inc.*, No. 14-CV-10201-IT, 2015 WL 1505693, at *9 (D. Mass. Mar. 31, 2015) (statement that "the FDA's feedback was the 'type of information that every company hopes for which is an encouraging sign from the FDA that a mid-stage trial, a phase II study is strong in enough to consider for an NDA filing'" is "not materially misleading merely because Plaintiffs seem to take issue with the general rosy picture that defendants attempted to paint" (internal quotation marks and alteration omitted)),

[12] To the extent Plaintiffs challenge the forward-looking nature of these statements—*i.e.*, that they are purportedly conveying an expectation regarding future FDA action—they are inactionable under the PSLRA's safe harbor. *See* section III.A.3.a *infra.* Dr. Sawhney used language such as "we believe" and "we think" (Compl. ¶¶ 69, 71) and Ocular noted that it would be making forward-looking statements and provided meaningful cautionary language. *See* Ex. G at 2 ("We believe we have taken the appropriate steps to address the manufacturing-related items raised by the FDA, although the FDA will make its determination after we resubmit our NDA."); *id.* ("Adequate resolution of the outstanding Form 483 manufacturing deficiencies is a prerequisite to the approval of the NDA . . . ."). *See Slayton v. Am. Express Co.*, 604 F.3d 758, 769 (2d Cir. 2010).

*aff'd*, 868 F.3d 31 (1st Cir. 2017).

**b) Statements Of Opinion Are Inactionable Absent Facts Showing Subjective Falsity**

The challenged statements from the November 9, 2016 earnings call (including those mentioned just above as puffery) also are protected statements of opinion, as they express Ocular's belief that it had taken adequate steps to address the FDA's observations. Compl. ¶ 69 ("*We believe* we have taken the appropriate steps to address the manufacturing related items raised by the FDA . . . ." (emphasis added)); *id.* ¶ 71 ("[W]e've adequately *we think* addressed the issues that they've raised . . . ." (emphasis added)).

These expressions of opinion are not actionable because Plaintiffs have failed to plead facts showing that the person holding the opinion subjectively did not believe the statement or lacked any objective basis for believing it.[13] *See Cody v. ConforMIS, Inc.*, 199 F. Supp. 3d 409, 419 (D. Mass. 2016) (statement that "we believe [certain facilities] are compliant with the FDA's [requirements]" is "an unvarnished opinion. Indeed, that is likely why 'we believe' was used, and a reasonable investor would understand that"); *see also Harrington v. Tetraphase Pharm. Inc.*, No. CV 16-10133-LTS, 2017 WL 1946305, at *5 (D. Mass. May 9, 2017) ("[C]ourts have been clear that scientific opinions are just that: opinions.").

The Complaint pleads no contemporaneous facts supporting the notion that, at the time of the November 9, 2016 earnings call, Dr. Sawhney (or any other Defendant) did not believe that Ocular would be able to resolve the FDA's inspectional observations. *See In re Praecis Pharm.*, 2007 WL 951695, at *9 (the "PSLRA ratchets the bar even higher: the facts pled by the plaintiffs

[13] *See Corban*, 2015 WL 1505693, at *6 (opinions are not actionable "unless Plaintiffs can allege that (1) the company's opinions were both objectively and subjectively false, *i.e.*, that the person holding the opinion did not subjectively believe in it, (2) self-embedded facts within the opinion are untrue, or (3) 'material facts about the opinion holder's inquiry into or knowledge concerning a statement of opinion' were omitted" (internal alterations omitted)) (citing *Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 135 S. Ct. 1318, 1329 (2015)).

must be sufficient to raise a strong inference that the issuer of the statement had actual knowledge of the statement's falsity"). Plaintiffs offer no reliable confidential witness statements or contemporaneous internal documents in support of this assertion. This is unsurprising, given that the only reasonable inference the record permits is that Dr. Sawhney believed the opinions he expressed. By the time of the earnings call, the FDA had already issued a letter to Ocular regarding the corrective actions that Ocular had proposed in the Company's response to the February 2016 Form 483. As Ocular described in its August 9, 2016 Form 8-K—which, tellingly, Plaintiffs choose not to quote in their Complaint—the FDA letter indicated that the corrective actions as a whole "appear to address the ten inspectional observations raised in the [February 2016] Form 483 with one exception which relates to the proposed process for identity testing of an incoming inert gas component used in the DEXTENZA manufacturing process." Ex. C at 1.[14] Thus, Ocular had ample grounds for optimism about its ability to address the FDA's observations and support for its statement that the FDA seemed to be in "broad agreement" with Ocular's corrective action plans. Compl. ¶ 71. *A fortiori*, the Complaint fails to plead that Ocular did not actually believe that it could adequately address the FDA's observations or had no objective basis to believe that it could do so.

Finally, unable to offer contemporaneous facts to undercut Ocular's expressions of optimism and belief, Plaintiffs again resort to impermissible hindsight pleading. According to Plaintiffs, Ocular's November 2016 statements about its progress in addressing the FDA's observations must have been false (or made without a reasonable basis) given that the FDA issued inspectional observations about manufacturing issues again in May 2017. *See* Compl. ¶¶ 5-7, 49-56. Putting aside the hindsight nature of the argument, it fails because it depends on the

[14] Indeed, Dr. Sawhney referenced this letter "from the New England district office" when he expressed the opinions at issue. Compl. ¶ 69.

flawed premise that the February 2016 FDA inspectional observations simply carried over, unresolved, to the May 2017 Form 483. The record reveals this is not so. First, as discussed above, in August 2016 the FDA advised Ocular that the Company's corrective action plans appeared to address all but one of the observations from the February 2016 Form 483. Second, the so-called "bombshell finding" in the May 2017 Form 483 regarding particular matter appears nowhere in Plaintiffs' allegations about the February 2016 Form 483. Thus, Plaintiffs fail even in their attempt to use hindsight to cast doubt on the veracity (or reasonableness) of Ocular's November 2016 statements.

**3. The Challenged Statements From The May 5, 2017 Earnings Call Are Not Actionable**

Plaintiffs challenge a number of statements Dr. Sawhney or Mr. Ankerud made during Ocular's May 5, 2017 earnings conference call regarding the May 2017 Form 483 and the Company's expectation that it could address the FDA's observations and obtain approval in a timely manner. Compl. ¶¶ 75-79. These claims fail for several reasons.

**a) The PSLRA's Safe Harbor Protects The Challenged Forward-Looking Statements**

Many of the challenged statements from the May 5, 2017 earnings call are forward-looking statements about the expected resolution of the FDA's inspectional observations and the prospects for FDA approval of DEXTENZA. Compl. ¶ 75 ("[W]e believe that each of the observations raised by FDA during this continuous improvement review of our fully developed manufacturing process are handled well and will be resolved in our response to FDA."); *id.* ("[W]e're marching toward that PDUFA date and expect that we can resolve the 4[8]3 issues in a timely manner."); *id.* at ¶ 79 (Q: "Is there anything in their observations that you think could delay the action date specifically?" A: "Nothing that we can currently see.").

Courts have consistently deemed these sorts of statements forward-looking and

inactionable under the PSLRA's safe harbor. *See Slayton v. Am. Express Co.*, 604 F.3d 758, 769 (2d Cir. 2010) ("[T]he use of linguistic cues like 'we expect' or 'we believe,' when combined with an explanatory description of the company's intention to thereby designate a statement as forward-looking, generally should be sufficient to put the reader on notice that company is making a forward-looking statement.") (internal quotation marks omitted); *Harrington*, 2017 WL 1946305, at *10 ( "We . . . continue to target submission of a new drug application, or NDA, for both indications by year end" is a forward-looking statement); *Ratner v. Ovascience, Inc.*, 134 F. Supp. 3d 621, 630 & n.9 (D. Mass. 2015) ("we plan to begin generating revenues," "[w]e do not believe we will be required to seek premarket approval," and we "continue[] to believe that [product] qualifies as a [defined regulatory term]; however the FDA could disagree" are all forward-looking statements).[15]

Ocular specifically identified these statements as forward-looking and provided meaningful cautions with the statements. At the start of the conference call, Ocular stated that management would be making forward-looking statements and warned that these statements involved material risks and uncertainties that were detailed in the Company's SEC filings:

> As a reminder, during today's call, we will be making certain forward-looking statements. Various remarks that we make during the call about the company's future expectations, plans and prospects do—these do constitute forward-looking statements for purposes of the Safe Harbor provisions under the Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by these forward-looking statements as a result of various important factors, including those discussed in the Risk Factors section of our most recent annual report or our actual report on Form 10-Q which was filed earlier this morning with the SEC. In addition, any forward-looking statements represent our views only as of today and should not be relied upon as representing our views as

[15] The PSLRA safe harbor protects statements when they are either: (a) identified as forward-looking statements and accompanied by meaningful cautionary language or (b) the plaintiff fails to prove that the forward-looking statement was made with actual knowledge that the statement was false or misleading. *See* 15 U.S.C. § 78u-5(c)(1). The two prongs of the safe harbor are disjunctive, so that a defendant is immune from liability if either prong is met. *See Greebel v. FTP Software, Inc.*, 194 F.3d 185, 201 (1st Cir. 1999). As set out herein, Plaintiffs also fail to plead that the Individual Defendants made any statement with the requisite scienter. *A fortiori*, the Complaint fails to plead that they made these forward-looking statements with actual knowledge of their falsity. *See* 15 U.S.C. § 77z-2(c)(1)(B).

> of any subsequent date. While we may elect to update these forward-looking statements at some point in the future, we specifically disclaim any obligation to do so, even if our views change.

Ex. D at 1-2. *See, e.g.*, *In re Parametric Tech. Corp. Sec. Litig.*, 300 F. Supp. 2d 206, 219 (D. Mass. 2001) (conference call's short cautionary statement regarding forward-looking statements and associated risks sufficient to trigger PSLRA safe harbor).[16]

In turn, Ocular specifically warned in its SEC filings—including in the Form 10-Q that Ocular filed on the same day as the earnings call in question—that "[a]dequate resolution of the outstanding Form 483 inspectional observations . . . is a prerequisite to the approval of the NDA for DEXTENZA . . . ."); Ex. F at 17; *see also id.* at 34 ("If we are unable to resolve these inspectional observations in a timely manner, potential approval of the NDA would be delayed or prevented."). Ocular provided similar warnings in its SEC filings throughout the class period, including warnings specific to the risks and anticipated timing of regulatory approval. *See, e.g.*, Ex. H at 99 ("Even if we complete the necessary preclinical studies and clinical trials, the regulatory approval process is expensive, time-consuming and uncertain and may prevent us from obtaining approvals for the commercialization of some or all of our product candidates.").[17]

Courts in this Circuit have found similar forward-looking statements and detailed, company-specific risk disclosures sufficient to trigger safe harbor protection. *See Harrington*, 2017 WL 1946305, at *9 (conference call disclaimers that noted presence of forward-looking statements and that referred to risk factors described in SEC filings sufficient to trigger PSLRA's safe harbor for forward-looking statements relating to NDA resubmission, market strength, and

[16] In addition, Ocular management specifically warned the call participants that timely FDA approval was not a foregone conclusion because Ocular needed to resolve the FDA's observations first. Ex. D at 2 ("A timely resolution of the 483 observations is a prerequisite to keep the PDUFA date on track."). This warning, which "explicitly identif[ies] the salient risk," also triggers safe harbor protection. *In re Sanofi Sec. Litig.*, 87 F. Supp. 3d at 536.

[17] *See also* Ex. A at 101-105 (discussing "Risks Related to Regulatory Approval" of Ocular's drug candidates).

other topics); *Coyne v. Metabolix, Inc.*, 943 F. Supp. 2d 259, 266 (D. Mass. 2013) ("we cannot assure you that we will be able to successfully manufacture [product] at a commercial scale in a timely or economical manner or that the quality of the commercial product will be acceptable on a consistent basis" meaningfully protects predictions regarding sales targets); *Meyer v. Biopure Corp.*, 221 F. Supp. 2d 195, 203-04 (D. Mass. 2002) (finding language in press release that discloses possibilities that clinical trials may not succeed, regulatory approvals may not be obtained, and that product may not find market acceptance sufficient to trigger safe harbor).[18]

**b) The Challenged Statements of Corporate Optimism and Opinion Are Not Actionable**

The remaining challenged statements from the May 5, 2017 earnings call are either expressions of corporate optimism or opinion, which are inactionable for the reasons discussed in sections III.A.2.a and III.A.2.b above. For example, Plaintiffs challenge Ocular's optimism that its manufacturing process improvements would be sufficient to resolve the FDA's inspectional observations. *See* Compl. ¶ 77 ("So I think that's *a strong sign* that the manufacturing process has *moved forward significantly*, and is in a *fully developed mode*." (emphasis added)). As noted above, such "rosy affirmations" are inactionable as a matter of law. *See* section III.A.2.a *supra*.

The challenged opinion statements also are not actionable. *See* Compl. ¶ 75 ("*We feel quite comfortable* that we have the situation under control."); *id.* ("[*W*]*e believe* that each of the observations raised by FDA during this continuous improvement review of our fully developed manufacturing process are handled well and will be resolved in our response to FDA."); *id.* ("[W]e're marching toward that PDUFA date and *expect* that we can resolve the 4[8]3 issues in a

[18] To the extent the Safe Harbor does not protect any challenged forward-looking statement, the bespeaks-caution doctrine nonetheless immunizes it. *See Shaw v. Digital Equip. Corp.*, 82 F.3d 1194, 1213 n.23 (1st Cir. 1996) (bespeaks caution doctrine "has been codified in the Securities Litigation Reform Act"); *In re Cytyc Corp. Sec. Litig.*, No. 02-12399-NMG, 2005 WL 3801468, at *21 (D. Mass. Mar. 2, 2005) (bespeaks-caution doctrine is "analogous" to Safe Harbor and protects "forward looking statement . . . if accompanied by adequate cautionary disclosures").

timely manner."); *id.* at ¶ 77 ("So *I think* that's a strong sign that the manufacturing process has moved forward significantly, and is in a fully developed mode.") (emphasis added in all quotations).[19] Here again, because Plaintiffs offer no contemporaneous facts to support the required inference that, at the time of the May 5, 2017 earnings call, Ocular did not believe it could resolve the FDA's inspectional observations, these challenged opinion statements are not actionable. *See* section III.A.2.b *supra; Cody*, 199 F. Supp. 3d at 419.[20]

**c) The Challenged May 5, 2017 Statements Are Not Misleading By Omission**

Plaintiffs' omission claim fares no better. Compl. ¶ 76 (the Company "mentioned certain problems identified in the [May 2017] Form 483, but omitted mention of even greater problems identified in that Form."); ¶ 78 ("the Company failed to disclose the very serious problems identified in the Form 483 or to characterize the problems identified in the Form 483 as very serious."). As described in section III.A.1 *supra*, far from downplaying the significance of the May 2017 Form 483, Ocular provided detailed disclosures regarding the substance of the FDA's inspectional observations, including the so-called "bombshell finding" regarding particulate matter, and provided these disclosures *on the same day as the challenged statements*. Nothing more was required. Ocular had no duty to disparage itself, characterize the FDA's observations in any particular way, or disclose every last detail regarding the May 2017 Form 483 or the Company's discussions with the FDA. *See Coyne*, 943 F. Supp. 2d at 269 ("A defendant does not have a duty to cast the descriptions of its business in the most negative light."); *Guerra v. Teradyne Inc.*, No. 01-11789-NG, 2004 WL 1467065, at *10 (D. Mass. Jan. 16, 2004) (company has no duty to disparage its own competitive position in market where it has provided accurate

[19] Although the Complaint (at ¶ 75) also highlights the statement that "we are preparing our responses to the 4[8]3 as of this morning in anticipation of responding within 15 calendar days to the agency," Plaintiffs do not assert that this statement is somehow inaccurate.

[20] As explained below, Plaintiffs' confidential witness allegations fail to fill this pleading gap.

hard data from which analysts and investors can draw their own conclusions); *Johnson v. Pozen Inc.*, No. 07-cv-599, 2009 WL 426235, at *19 (M.D.N.C. Feb. 19, 2009) (no duty to disclose "every detail of [defendant's] FDA correspondence," even where they included safety concerns).

**4. The Allegations Regarding The Sole "Confidential Witness" Are Neither Reliable Nor Sufficiently Particularized And Do Not Render Any Challenged Statement False**

Plaintiffs' Confidential Witness ("CW") allegations do nothing to establish the falsity of any challenged statement. Compl. ¶¶ 46, 103-04. The Complaint fails to establish the CW's reliability or his or her qualifications to opine on any relevant issue.

Courts may only credit confidential witnesses if "they are described in the complaint with sufficient particularity to support the probability that a person in the position occupied by the source would possess the information alleged." *New Jersey Carpenters Pension & Annuity Funds v. Biogen IDEC Inc.*, 537 F.3d 35, 51 (1st Cir. 2008) (quoting *In re Cabletron Sys. Inc.*, 311 F.3d 11, 29 (1st Cir. 2002)). The Court must conduct an "evaluation, inter alia, of the level of detail provided by the confidential sources, the corroborative nature of the other facts alleged (including from other sources), the coherence and plausibility of the allegations, the number of sources, the reliability of the sources, and similar indicia." *Id.*

The Complaint fails to establish the reliability of the confidential witness allegations. The Complaint contains only the CW's job title (Regulatory Affairs Project Manager), without any description of his or her job duties and responsibilities. Plaintiffs do not even allege that the CW had any role regarding the DEXTENZA NDA or drug manufacturing, let alone with respect to addressing the FDA's inspectional observations. *See* Compl. ¶ 46. This is plainly insufficient. *See In re Possis Med., Inc., Sec. Litig.*, No. 05-CV-1084 (JMR/FLN), 2007 WL 335051, at *5 (D. Minn. Feb. 1, 2007) ("[b]eyond the source[s]' job title[s], [P]laintiffs . . . have not described with any kind of specificity the source's job description or responsibilities."), *aff'd sub nom.*

*Cornelia I. Crowell GST Tr. v. Possis Med., Inc.*, 519 F.3d 778 (8th Cir. 2008); *Phillips v. Triad Guar., Inc.*, No. 1:09CV71, 2015 WL 1457980, at *5 (M.D.N.C. Mar. 30, 2015) ("simply alleging the confidential source's vague title [*i.e.*, Vice President of Risk Analytics], employment period, and the individuals to whom he reported," is not a sufficient basis for reliability).

In any event, Plaintiffs' allegations fail to establish that the CW has firsthand knowledge relevant to any challenged statement. The CW purportedly worked at Ocular for only a short time, from November 1, 2016 until late February or early March of 2017. Compl. ¶ 46. Thus, his or her employment at Ocular began well after many of the relevant events had already transpired, including the issuance of the February 2016 Form 483 and Ocular's efforts to resolve those observations. The CW also allegedly joined Ocular *just eight days* before the November 9, 2016 earnings call, and Plaintiffs' offer no allegations to reasonably suggest that this individual gained information during these eight days that bears on the veracity of any statement that Dr. Sawhney made during that earnings call. *In re Vertex Pharm. Inc., Sec. Litig.*, 357 F. Supp. 2d 343, 353 (D. Mass. 2005) ("Most significantly, none of the CWs claims to have personal knowledge of the most important facts they allege. Only CW1 worked at Vertex during the entire duration of the Class Period. CW2 arrived at Vertex after the Class Period, and CW3, CW4, and CW5 were at Vertex only during the latter half of the Class Period.").

While the CW's alleged knowledge thus only could be relevant to the challenged March 2017 cGMP statement and the May 5, 2017 earnings call statements, Plaintiffs' allegations once again fall well short of demonstrating that the CW has knowledge about any relevant issue. The Complaint attributes a single allegation to the CW: that he or she had a "direct conversation" with Mr. Ankerud "in late 2016 or early 2017," during which Mr. Ankerud purportedly "acknowledged that he and the Company knew Ocular would be including batch records in the

NDA resubmission that would not meet FDA standards." Compl. ¶ 46. Even taking this statement at face value, it does not render false any challenged statement:

*First*, because this alleged conversation about the batch records to be included in the DEXTENZA NDA has nothing to with cGMP compliance (and Plaintiffs do not suggest otherwise), it is entirely irrelevant to the challenged March 2017 cGMP statement.

*Second*, this conversation and the CW's alleged knowledge also have no bearing on the challenged statements from the May 5, 2017 earnings call, which concern the Form 483 that the FDA issued to the Company on May 4, 2017. According to Plaintiffs, the CW left Ocular at "the end of February 2017 or early March 2017." Compl ¶ 46. But the FDA conducted the inspection that culminated in the May 2017 Form 483 between April 24, 2017 and May 4, 2017 (*id*. ¶ 46), *which is after the CW left Ocular*. Because the CW has no personal knowledge of the FDA inspection, the observations the FDA made during that inspection, and Ocular's plans to address those observations, the CW could not possibly have credible, particularized knowledge bearing on the statements Ocular made about those subjects during the May 5, 2017 earnings call. *See In re Vertex Pharm.*, 357 F. Supp. 2d at 353 (confidential witness allegations insufficient where "none of the CWs claims to have personal knowledge of the most important facts they allege"); *see also Hensley v. Imprivata, Inc.*, 260 F. Supp. 3d 101, 121-22 (D. Mass. 2017) (explaining that allegations from a confidential witness who lacked "firsthand knowledge" of management's state of mind "are of minimal value").

Even so, the one issue that the CW purportedly discussed with Mr. Ankerud—the alleged sufficiency of the batch records that Ocular included in its NDA resubmission—does not make any challenged statement false or misleading. None of the FDA's inspectional observations—including the so-called "bombshell finding" regarding particulates—relates to FDA standards for

batch records. Nor does the Complaint explain how, if at all, the inclusion of such batch records might impact the prospects for DEXTENZA approval. *See In re Lululemon Sec. Litig.*, 14 F. Supp. 3d 553, 580 (S.D.N.Y. 2014) (even accepting as true CW allegations that quality testing "was not 'regular' but rather 'random at best' and that such testing was done on 'a new [product]' but not on a 'regular [product]' . . . they do not substitute for well-pleaded allegations of contemporaneous falsity—that the makers of the statements about product quality knew their statements were false or misleading at the time they were made").

### B. Messrs. Hurley and Migausky Are Not Liable For Statements They Did Not Make And Over Which They Had No Control

Plaintiffs' claims against Messrs. Hurley and Migausky (Ocular's former Chief Commercial Officer and former interim Chief Financial Officer, respectively) fail for an additional reason: they did not make or have any control over any of the challenged statements. "Only the 'maker' of a fraudulent statement may be held liable under Section 10(b)." *Universal Am. Corp. v. Partners Healthcare Sols. Holdings, L.P.*, 176 F. Supp. 3d 387, 393 (D. Del. 2016); *see also Sodhi v. Gentium S.p.A.*, No. 14-CV-287 (JPO), 2015 WL 273724, at *3 (S.D.N.Y. Jan. 22, 2015) (noting that "[t]o be liable under Section 14(e), the defendant must 'make' the allegedly fraudulent statement or control the person who does."); *In re Textron, Inc., S'holder Deriv. Litig.*, 811 F. Supp. 2d 564, 574 (D.R.I. 2011) (individual defendants cannot be held liable if the complaint does not allege that they made any of the statements underlying the claims). "[T]he maker of a statement is the person or entity with *ultimate authority* over the statement, including its content and whether and how to communicate it." *Janus Capital Grp., Inc. v. First Deriv. Traders*, 564 U.S. 135, 142 (2011) (emphasis added).

Plaintiffs do not allege that Messrs. Hurley or Migausky had any role whatsoever in the composition, approval, or dissemination of any of the challenged statements. Indeed, Mr.

Migausky did not even join Ocular until April 6, 2017 (*see* Ex. I at 2) which post-dates every challenged statement other than the May 5, 2017 conference call statements (for which he is not a speaker). *See Bartesch v. Cook*, 941 F. Supp. 2d 501, 511 (D. Del. 2013) ("[N]o fraud liability can exist against any defendant who was not a director or officer of [defendant corporation] at the time of the challenged statement."). As neither Mr. Hurley nor Mr. Migausky made any challenged statement, and because the Complaint is devoid of allegations that either of them had authority over any challenged statement, the Court should dismiss all claims against them. *See also Janus Capital Grp.*, 564 U.S. at 142.

**C. The Complaint Does Not Raise The Required Strong Inference Of Scienter**

The PSLRA requires that Plaintiffs allege particularized facts raising a "strong inference" that the Defendants either (1) acted with "conscious intent to defraud or a high degree of recklessness" or (2) had both motive and opportunity to commit the fraud. *Urman v. Novelos Therapeutics, Inc.*, 796 F. Supp. 2d 277, 283 (D. Mass. 2011) (internal quotation marks omitted) (citing *ACA Fin. Guar. Corp. v. Advest, Inc.*, 512 F.3d 46, 58 (1st Cir. 2008)); *see In re Sonus Networks, Inc., Sec. Litig.*, No. 04-10294-DPW, 2006 WL 1308165, at *12-13 (D. Mass. May 10, 2006) (Plaintiffs must "set . . . forth specific facts that make it reasonable to believe that defendant[s] knew that a statement was false or misleading" or "that [the individual] defendants had full knowledge of the dangers of their course of action and chose not to disclose those dangers to investors," through facts showing, among other things, motive and opportunity) (internal citations and quotation marks omitted)). An inference of scienter is only "strong" if a reasonable person would deem it "cogent and at least as compelling as any opposing inference." *In re Ariad Pharm., Inc., Sec. Litig.*, 98 F. Supp. 3d 147, 158 (D. Mass. 2015), *aff'd in part, rev'd in part*, 842 F.3d 744 (1st Cir. 2016). The Complaint does not contain any particularized

allegations from which the Court could draw the required strong inference of scienter as to any Individual Defendant.[21]

### 1. Plaintiffs Allege No Specific Facts Showing That Any Individual Defendant Knew Or Was Reckless In Not Knowing That Any Statement Was False When Made

Plaintiffs premise the Complaint on the claim that Ocular "knew" that its manufacturing process was not cGMP-compliant and that it would not be able to resolve the inspectional observations that the FDA identified in a timely manner. For the same reasons that Plaintiffs fail to establish a false or misleading statement in the first instance, they necessarily fail to establish that any challenged statement was knowingly or recklessly false or misleading. *See supra* at section III.A; *see also New Jersey Carpenters Pension & Annuity Funds v. Biogen IDEC Inc.*, 537 F.3d 35, 45 (1st Cir. 2008) ("A statement cannot be intentionally misleading if the defendant did not have sufficient information at the relevant time to form an evaluation that there was a need to disclose certain information and to form an intent not to disclose it."); *DeMarco v. DepoTech Corp.*, 149 F. Supp. 2d 1212, 1232 (S.D. Cal. 2001) (without a false statement, scienter analysis "entails the illogical inquiry into whether the defendant intended to deceive when, in fact, there was no deception").

In any event, "[i]n cases where [courts] have found the pleading standard satisfied, the complaint often contains clear allegations of admissions, internal records or witnessed discussions suggesting that at the time they made the statements claimed to be misleading, the defendant officers were aware that they were withholding vital information or at least were warned by others that this was so." *In re Bos. Sci. Corp. Sec. Litig.*, 686 F.3d 21, 31 (1st Cir.

[21] Because corporate liability "is ascertained through the mental state of [their] management," it follows that the claims against the Company likewise fail. *See Isham v. Perini Corp.*, 665 F. Supp. 2d 28, 36 (D. Mass. 2009) (citation and quotations omitted).

2012). Such allegations are lacking here, as instead Plaintiffs rely only on insufficient rhetoric, conclusions, and hindsight.

The conclusory allegations that the Individual Defendants "each knew," "must have known," or "could not have been unaware" of the falsity of the challenged statements (*see* Compl. ¶¶ 93, 98-101) cannot substitute for particularized facts supporting those assertions. *See In re Stone & Webster, Inc., Sec. Litig.*, 414 F.3d 187, 214 (1st Cir. 2005) (scienter is not pled by "a conclusory assertion that the defendant knew the true facts, or knew that the challenged statement was false. What is needed is the allegation of particularized facts which give strong support to that conclusion"); *In re Praecis Pharm., Inc. Sec. Litig.*, No. 04-12581-GAO, 2007 WL 951695, at *9 (D. Mass. Mar. 28, 2007) (rejecting "must have known" allegations as insufficient).[22] Similarly, the Plaintiffs' allegations that the Individual Defendants, by virtue of their titles and accompanying responsibilities, were "privy to" material information (Compl. ¶¶ 98-101) is quintessential "scienter by status" pleading; courts universally reject "[g]eneral inferences that the defendants, by virtue of their position within the company, 'must have known' about the company's problems." *Urman*, 796 F. Supp. 2d at 283; *see also Maldonado v. Dominguez*, 137 F.3d 1, 10 (1st Cir. 1998) ("general inferences that [defendants] 'must have known' [based on their positions]… are precisely the types of inferences which this court, on numerous occasions, has determined to be inadequate"); *In re Sonus Networks*, 2006 WL 1308165, at *22 ("fraudulent intent cannot be inferred merely from the Individual Defendants' positions in the Company and alleged access to information").

Plaintiffs also attempt to invoke the "core operations" doctrine. Compl. ¶ 102. This is a

[22] With respect to the challenged cGMP statements, Plaintiffs allege that the mere receipt of the February 2016 and May 2017 Form 483s was enough to establish knowledge of the falsity of these statements. Compl. ¶ 29. However, as discussed above, the Form 483s do not reflect final FDA determinations, and thus cannot give rise to strong inference of scienter regarding cGMP compliance. *See* section III.A.1 *supra*.

very narrow exception to the no-scienter-by-status rule, by which some courts have imputed knowledge of facts to corporate officials because the subject matter is so crucial to the company's operations that it is fair to infer that they knew them. *See In re A123 Sys., Inc. Sec. Litig.*, 930 F. Supp. 2d 278, 285-86 (D. Mass. 2013). However, whether the "core operations" exception applies here is irrelevant because Plaintiffs have not pleaded a single particularized fact that—even assuming the Individual Defendants knew it—would give rise to an inference that they knew any challenged statement was false or misleading. *See In re Psychemedics Corp. Sec. Litig.*, No. CV 17-10186-RGS, 2017 WL 5159212, at *6 (D. Mass. Nov. 7, 2017) (disregarding plaintiff's "core operations" doctrine theory because plaintiff's "theory stands naked, unadorned by any other piece of evidence purporting to establish the essential 'plus' factor", *i.e.*, particularized facts).

Finally, Plaintiffs seek to establish scienter based on their confidential witness allegations. Compl. ¶ 103.[23] However, as established above, the CW's allegations (1) are not reliable given the deficiency of Plaintiffs' pleading and (2) are wholly irrelevant to the subject matter of the challenged statements given the CW's brief tenure at Ocular and the limited scope of the CW's allegations. *See* section III.A.4 *supra*. In sum, the CW's allegations regarding the purported insufficiency of the batch records to be included in Ocular's NDA resubmission do not support any inference, let alone a "strong" inference, that Mr. Ankerud acted with scienter.

**2. Plaintiffs Offer No Motive Allegations**

Notably lacking from Plaintiffs' Complaint are any allegations that the Individual

[23] Because the Complaint does not allege that the CW had any contact or communications with any defendant other than Mr. Ankerud, the CW allegations cannot contribute to an inference of scienter as to Dr. Sawhney or Messrs. Migausky or Hurley—and in any event, does not support an inference as to Mr. Ankerud's scienter either. *In re Wachovia Equity Sec. Litig.*, 753 F. Supp. 2d 326, 352 (S.D.N.Y. 2011) ("[T]here is no allegation that any CW met the Individual Defendants, reported any concerns, received any instructions, or made any personal contact with them during the Class Period. The absence of such communication undermines the inference that Defendants recklessly disregarded the truth . . . . ").

Defendants had a "motive" to commit fraud. There is no allegation that any Individual Defendant sold a single share of stock during the class period, which undercuts any scienter inference. *See In re Glenayre Techs. Inc. Sec. Litig.*, No. 96 CIV. 8252 (HB), 1998 WL 915907, at *4 (S.D.N.Y. Dec. 30, 1998) ("the inference of scienter is undermined by the fact that . . . [company executives] did not sell any stock"); *In re Stone & Webster, Inc. Sec. Litig.*, 253 F. Supp. 2d 102, 128 (D. Mass. 2003) ("most cases in which courts have found motive and opportunity to be present involve the sale of stock by defendants at artificially inflated prices"); *See also In re CIENA Corp. Sec. Litig.*, 99 F. Supp. 2d 650, 662 (D. Md. 2000) ("[Defendant] did not sell a single share of his stock during the class period. Thus, his motive could not have been to inflate the value of [the company's] stock . . . ."). To the contrary, Dr. Sawhney actually purchased additional shares during the class period.[24] *See* Exs. J and K; *Fire & Police Pension Ass'n of Colo*, 778 F.3d at 246 (individual defendant's increase in stock holdings "negates any inference that he had a motive to artificially inflate [the company's] stock during" class period); *In re First Union Corp. Sec. Litig.*, 128 F. Supp. 2d 871, 898-99 (W.D.N.C. 2001) (increase in holdings of two insiders during class period demonstrated absence of scienter). By failing to plead that the Individual Defendants had a motive to commit fraud, Plaintiffs tacitly admit that the circumstances typically supporting a finding of scienter are not present here.

**D. Plaintiffs' Claim For Control Person Liability Fails**

Failing to plead a primary violation, Plaintiffs' Section 20(a) "control person" claim also must fail. *ACA Fin. Guar. Corp.*, 512 F.3d at 67 ("The plain terms of section 20(a) indicate that it only creates liability derivative of an underlying securities violation"); *In re First Marblehead*

[24] Dr. Sawhney's Form 4s may be considered here as a public record. *See, e.g., In re Colonial Mortg. Bankers Corp.*, 324 F.3d 12, 19 (1st Cir. 2003) ("[M]atters of public record are fair game in adjudicating Rule 12(b)(6) motions, and a court's reference to such matters does not convert a motion to dismiss into a motion for summary judgment.").

*Corp. Sec. Litig.*, 639 F. Supp. 2d 145, 165 (D. Mass. 2009) (dismissing control-person claim for same reason).[25]

## IV. CONCLUSION

For all the foregoing reasons, the Court should dismiss the Consolidated Amended Class Action Complaint in its entirety, with prejudice.

Respectfully Submitted,

Dated: July 6, 2018

*/s/ Peter J. Kolovos*

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[25] To the extent Plaintiffs seek to impose control person liability on Mr. Migausky for statements others made before he joined Ocular (*see* section III.B supra), the Section 20(a) claim against him also fails for this reason.

**CERTIFICATE OF SERVICE**

I hereby certify that a copy of the foregoing was served on the participants of the ECF system in the above-captioned matter on July 6, 2018.

Dated: July 6, 2018

*/s/ Peter J. Kolovos*
Peter J. Kolovos